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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/069,385 | 02/19/2002 | Paul Robert Atkinson | X-13268 | 3249 |

25885 7590 03/30/2005
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EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/069,385 | Applicant(s) ATKINSON ET AL. | |
| | Examiner Eileen O'Hara | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 December 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-16 and 19-21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14-16 and 19-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

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DETAILED ACTION

1. Claims 14-16 and 19-21 are pending in the instant application. Claims 14 and 19 have been amended and claims 17-18 have been canceled as requested by Applicant in the Paper filed December 13, 2004.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Specification

3. The disclosure remains objected to because of the following informalities.

3.1 On page 5, lines 16-17, SEQ ID NO: 3 is defined as a protein but is a nucleic acid in the sequence listing.

Appropriate correction is required.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1 Claims 14-16 and 19-21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a FLINT analog that is

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protease resistant to proteolysis between positions 218-219 of SEQ ID NO: 1 (mature form) or positions 247 and 248 of SEQ ID NO: 3 (full-length or native) and divalent cations, does not reasonably provide enablement for other FLINT analogs, for reasons of record in the previous office action, mailed June 28, 2004 at pages 3-6, and below.

4.2 Claims 14-16 and 19-21 also remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous office action, mailed June 28, 2004 at pages 6-8, and below.

Applicants have amended the claims to specify a particular site within the FLINT molecule at which protease resistance occurs, namely between positions 218 and 219 of mature FLINT (SEQ ID NO: 1) or positions 247-248 of full-length FLINT (SEQ ID NO: 2). However, as amended, the claims still encompass polypeptides that vary substantially in amino acid composition, because there is no requirement that the FLINT analog has any particular amino acid structure. It is suggested that claim 14 be amended as follows:

Claim 14. A composition comprising a divalent metal cation and a protease-resistant FLINT analog, wherein said FLINT analog has an amino acid sequence that differs from the amino acid sequence of SEQ ID NO: 1 by substitution at residue 218, and optionally, by substitution at residues 34, 36, 194 and/or 196, or wherein said FLINT analog has an amino acid sequence that differs from the amino acid sequence of SEQ ID NO: 2 by substitution at residue 247, and optionally, by substitution at residues 63, 65, 223 and/or 225, wherein said FLINT

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analog is resistant to proteolysis between positions 218-219 of SEQ ID NO: 1 or positions 247-248 of SEQ ID NO: 2, and wherein said FLINT analog inhibits binding of FasL to Fas receptor.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14-16 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because claim 14 encompasses a composition comprising a protease-resistant FLINT analog resistant at proteolysis at position 247-248 of SEQ ID NO: 3, but SEQ ID NO: 3 is a nucleic acid molecule and not a protein.

It is believed that all pertinent arguments have been answered.

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

Elyse C. Kemmer

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